INSPECTION GUIDELINES

September 1, 2000

Controlled Substances in a Physical Therapy Department

A pharmacy can provide controlled substances to a patient in the physical therapy department upon receipt of a valid order from a physician. The drug must be appropriately labeled and used for the individual patient. The physical therapist cannot select a controlled substance from floor stock for patient use.

Making Changes to A Compliance Notice

The Compliance Notice must include all deficiencies noted during an inspection. The licensee must respond to the Board for each deficiency. The deficiency must be noted on the Compliance Notice even if it is corrected at the time of inspection. The inspector may note on the Inspection Report that the deficiency was corrected during the inspection. For example, the refrigerator is missing a thermometer but the licensee acquires and places a thermometer in the refrigerator before the inspection is completed.

A deficiency may be deleted (marked through) on a Compliance Notice if the inspector noted the deficiency and later discovered that the licensee is in compliance. For example, a licensee is unable to produce a required inventory but locates it after the inspector has prepared the Compliance Notice before the inspector leaves the facility

Inventory Requirement for A 24-hour Pharmacy

18 VAC110-20-240.Manner of maintaining records, prescriptions, inventory records

5. *All inventories required by § 54.1-3404 shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken*

§ 54.1-3404. Persons required to keep record of drugs; contents and form of record.

A. *Every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business*.

A new permit is issued to the incoming PIC when a new PIC is named so technically a new business inventory is required by § 54.1-3404. The incoming pharmacist-in-charge is responsible for clearly documenting whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

Rubber Stamping Drug Information On A Prescription

Other than the provision to use preprinted prescriptions fro drugs classified in Schedule VI, there is provision to allow the drug information on a prescription for Schedule II - V to be rubber stamped. §54.1-3401.1 of the Drug Control Act states that “The written prescription referred to in §54.1-3408 shall be written with ink or individually typed or printed". Additionally, §1306.05 of the Code of Federal Regulations states “prescriptions shall be written with ink or indelible pencil or typewriter”.

Inspection for a Manufacturer Permit

A hospital requests a Manufacturer permit to allow the repackaging of drugs for transfer to other facilities. Can the manufacturing function be performed within the established pharmacy area?

The manufacturing area may not operate from the pharmacy. It must be in a separate area. At the opening, the inspector inspects primarily for security. The FDA ususally does an opening inspection for compliance with GMPs shortly after the facility begin operations.

Virginia regulations adopt by reference the Good Manufacturing Practices set forth in 21 CFR 211. Where can information about GMP can be found?

Not all GMPs will apply to a repackager. During an opening inspection, there is nothing to inspect with respect to GMP's if the facility is not operational.

GMP information is available in the USPDI. Sections of the CFR (21CFR §210.1-211.208) are available at the the following sites.

http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr210_00.html

http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr211_00.html